UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Carmen Rodia

From: Dee Colby, Ph.D., Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Entomologist

Date: August 22, 2016

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 434872
Decision no.: 518516
Submission no: 987860
Action code: R340
Product Name: RF2233 267 DFB Granules
EPA Reg. No or File Symbol: 89459-82
Formulation Type: Granules
Ingredients statement from the label with PC codes included:
Diflubenzuron 2.67% PC: 108201

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m^2 or mg/cm^2 or mg/kg body weight as appropriate): for cattle 0.1 mg diflubenzuron/kg body weight/day; horses 0.15 mg/kg; swine 0.2-0.3 mg/kg

Use Patterns: As a feed-through for use in supplements, feeds, milk replacer, blocks, tubs, etc. to prevent emergence of house, stable, face, and horn flies.

I. Action Requested: Registrant requested an efficacy review of the submitted MRIDs to determine if data support product efficacy and associated claims for preventing the development of house flies and stable flies on manure of swine.

II. Background: Registrant is proposing an amendment requiring data review to support IGR claims for manure breeding house flies and stable flies for swine. Two MRIDs, one specific to RF2233 267 DFB Granules (MRID 49950701) and one generic to diflubenzuron (48809303) were submitted to support product efficacy claims for manure breeding flies (i.e., house, stable, face, and horn flies). MRID 48809303 has been reviewed twice before. It was originally reviewed for DP #s 421370, 421371, 421372, and 421369 in a review dated 09/11/2014 and again for DP #428964 in a review dated 01/12/2016 during registration of RF2233 267 DFB Granules.

III. MRID Summary:

MRID 48809303. Warner, W. (2012) Product Performance: RMI-2011-B.

(1) non-GLP

(4) **Conclusion:** This MRID is **supplemental.** MRID 48809303 was previously reviewed for RF2233 267 DFB Granules in a review dated 01/12/2016 (DP #428964). The review concluded that, "This study does not support any claims against house flies, face flies, stable flies, horn flies, and is rated supplemental."

MRID 49950701. Smythe, B.G. (2016) Efficacy of RF2233 267 DFB Granules against pest flies developing in manure of treated animals.

(1) non-GLP

(2) **Methods:** This was a live animal/lab study conducted at the NMSU Veterinary Entomology Research Lab. The study was conducted using 12 domesticated swine, 6 treated and 6 control, with relatively equal body weight between the two groups. Treated swine were dosed with 0.20 mg of diflubenzuron/kg of body weight/day (i.e., at label rate) mixed with feed daily for 9 d; controls were fed in the same manner minus the active ingredient. Manure (~400 g) from each animal was collected in bags beginning on day 0, pretreatment, through day 9. Manure samples were frozen to kill arthropod fauna that may have been present in feces prior to collection and then thawed prior to use. Each sample was divided into 6 bioassay cups (~50 g/cup), inoculated with 100 stable fly or house fly larvae each (n = 3 each, stable fly and house fly cups) and incubated for 3 weeks. Stable fly cups were amended with a stable fly medium to ensure stable fly development. Efficacy was calculated as: % Efficacy = (control average adult fly emergence – treatment adult fly emergence/control adult fly emergence) x 100.

(3) **Results:** A > 90% reduction in adult house fly (*Musca domestica*) and stable fly (*Stomoxys calcitrans*) emergence numbers was observed by day 4 of the treatment compared to controls. It was noted that the average emergence rates for controls did not exceed > 50% of the original inoculum; however, data showed that emergence in the treatments was at least one order of magnitude lower than the controls.

(4) **Conclusion:** This MRID is **acceptable**; daily doses of RF2233 267 DFB Granules at 0.20 mg of diflubenzuron/kg of body weight/day to swine reduced numbers of adult house flies and stable flies that emerged from manure during treatment by > 90% compared to controls. Treatment with RF2233 267 DFB Granules was administered daily in order to achieve and maintain efficacious levels of control. An acceptable level of efficacy at ≥ 90% reduction of adult flies was not observed until day 4 of treatment.

IV. EXECUTIVE DATA SUMMARY:

(A) The submitted data support that daily doses of RF2233 267 DFB Granules at 0.20 mg of diflubenzuron/kg of body weight/day to swine reduce numbers of adult house flies and stable flies that emerge from manure during treatment by > 90% compared to controls. Treatment with RF2233 267 DFB Granules must be administered daily in order to achieve and maintain efficacious levels of control. RF2233 267 DFB Granules is not a repellent or adulticide; it does not offer protection from adult house flies and stable flies. General fly claims (e.g., "manure breeding flies") or claims for other species of flies that are of public health concern are not supported by the data.

V. LABEL RECOMMENDATIONS:

(1) List changes to the directions for use. All DFU and claims must be specified so that it is clear that the product is efficacious against house flies, horn flies, stable flies and face flies for cattle; house flies and stable flies for horses; and house flies and stable flies for swine **or** referred to as 'listed' [(fly) (flies)] once species have been specified.

[RF2233 267 DFB Granules inhibits the development of listed fly larvae in the manure of treated [(cattle) (horses) (swine)].

[When fed to swine according to label directions, [(RF2233 267 DFB Granules) (This product) (Diflubenzuron)]

prevents the emergence of [house flies] [stable flies) ~~[manure breeding flies]~~ from the manure of treated swine].

Start feeding [(RF2233 267 DFB Granules)(This product)] early in the spring before listed flies begin to appear and continue feeding throughout the summer and into the fall until cold weather restricts fly activity.

This product is not effective against existing adult flies. When starting a feeding program during the listed fly season, it is desirable to use other control measures to reduce the population of existing adult flies.

In some cases, supplemental fly control measures for listed flies may be needed in and around [cattle] [horses] [swine]] ((lots)(buildings)(stalls)(barns)(paddocks){facilities)(sheds)(houses)] to control adult house flies and stable flies, which can breed not only in [swine][cattle][horse] manure, but in decaying vegetable matter or silage on the premises. In order to achieve optimum fly control for listed flies, use [(Brand Name) (this product)] in conjunction with other good management and sanitation practices.

The dosage of [(Brand Name) (this product)] is proportional to the animal's body weight and must be offered daily throughout the entire listed fly season. The following table [(gives dosage information) (provides the feeding rate)] for all approved species.

(2) The following marketing claims are acceptable:

For use in [(cattle), (equine) and (swine)] feeds and supplements as part of an integrated pest management program to control listed flies developing in manure and stored product pests developing in spilled treated feed

Provide to cattle [lactating and non-lactating beef and dairy cows, slaughter, stocker, and feeder cattle, and calves include veal calves] to [(stop) (prevent the)] [(development) (emergence)] of these specific flies: House flies, Stable flies, Face flies, and Horn flies

Provide to horses [including ponies, burros, and donkeys] to [(stop) (prevent the)] [(development) (emergence)] of these specific flies: House flies and Stable flies

Provide to swine [including nursery, grow-finish and breeding stock] to [(stop) (prevent the)] [(development) (emergence)] of these specific flies: House flies and Stable flies. ~~and other manure breeding flies.~~

[(Stops) (Prevents the)] [(development) (emergence)] of stored product pests, such as (Indian meal moth) (red flour beetle) (confused flour beetle) from treated feed

(Daily) feed concentrate [for (cattle) (horses) (swine)] containing [(diflubenzuron) (Insect Growth Regulator) (IGR) (a larvicide)] for continuous feeding during the listed fly season

Listed [(Fly larvicide) (fly control)] for [(cattle) (horses) (and) (swine)]

Contains [(diflubenzuron) (Insect Growth Regulator) (IGR) (chitin synthesis inhibitor) (a larvicide)] [for continuous feeding during the listed fly season]

Breaks the listed [(fly) (flies')] life cycle(s)

(Can be used as) part of [(an integrated)] [(fly) (pest)] management program

(3) The following marketing claims are unacceptable: General fly claims (e.g., “manure breeding flies”) are not supported by data.

(4) The following MRIDs should be removed from the data matrix, as they are classified as “unacceptable” to support the product: N/A

(5) Note to PM: Claims and DFU for non-public health pests are not reviewed for efficacy.